BIONICHE
ANIMAL HEALTH USA, INC.

August 20, 2004

Documents Management Branch (HFA–305), Room 1061
Food and Drug Administration,
5630 Fishers Lane,
Rockville, MD USA
20852

Suitability Petition
Intravaginal Progesterone Insert for Cattle

Dear Sir or Madam:

Please find enclosed a suitability petition for Agency review and action. Bioniche Animal Health USA, Inc., is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic intravaginal progesterone insert for cattle that differs from the pioneer product (EAZI-BREED™ CIDR®; NADA 141-200) in strength (i.e., concentration) of the active ingredient.

Your review of the enclosed petition would be greatly appreciated.

Please feel free to contact me at (613) 966-8058 should have any questions or require further information.

Sincerely,

Cindy Hickey
V.P. Corporate Quality & Regulatory Affairs
Bioniche Life Sciences Inc.

Enclosure

2004P-0376

CP1

Suitability Petition

Bioniche Animal Health USA, Inc.
Intravaginal Progesterone Insert for Cattle
August 20, 2004

The undersigned submits this petition under Section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of an application for the generic intravaginal progesterone insert for cattle that differs from the pioneer product (EAZI-BREED™ CIDR®; NADA 141-200) in strength of the active ingredient in the proposed drug product.

Action Request

We are requesting that the Commissioner permit the filing of an Abbreviated New Animal Drug Application (ANADA) for an intravaginal progesterone insert for cattle (trade name to be determined). The application will include a bioequivalence study. Our proposed product differs from the pioneer product as follows:

Pioneer Product

Trade Name

EAZI-BREED™ CIDR® Cattle Insert (NADA 141-200)

Active ingredients

Progesterone

Dosage form

Intravaginal Insert

Strength

Each insert contains 1.38 grams of progesterone in molded silicone (silastic) over a nylon spine.

Sponsor

DEC International, Inc.

Dosage

For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and

advancement of first pubertal estrus in beef heifers; administer one EAZI-BREED™ CIDR® Cattle Insert per animal for 7 days. Inject 5mL LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) 1 day prior to EAZI-BREED™ CIDR® Cattle Insert removal, on day 6 of the 7 day administration period. Observe animals for signs of estrus on days 1 and 3 after removal of the EAZI-BREED™ CIDR® Cattle Insert and inseminate animals about 12 hours after onset of estrus.

For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus, administer one EAZI-BREED™ CIDR® Cattle Insert per animal 14 ± 1 days after insemination and remove the EAZI-BREED™ CIDR® Cattle Insert 7 days later. Observe animals for signs of estrus on days 1 and 3 after removal of the EAZI-BREED™ CIDR® Cattle Insert and inseminate animals about 12 hours after onset of estrus.

Proposed Drug Product

Trade Name

CueMate

Active ingredients

Progesterone

Dosage Form

Intravaginal Insert

Strength

Each insert contains 1.56 gram of progesterone in molded silicone (silastic) over a nylon spine.

Sponsor

Bioniche Animal Health USA, Inc.

Dosage

For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers; administer one Cattle Insert per animal for 7 days. Inject 5mL LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) 1 day prior to Cattle Insert removal, on day 6 of the 7 day administration period. Observe animals for signs of estrus on days 1 and 3 after

removal of the Cattle Insert and inseminate animals about 12 hours after onset of estrus.

For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus, administer on Cattle Insert per animal 14 ± 1 days after insemination and remove the Cattle Insert 7 days later. Observe animals for signs of estrus on days 1 and 3 after removal of the Cattle Insert and inseminate animals about 12 hours after onset of estrus.

Statement of Grounds

The proposed generic product contains the same active ingredient and will be labeled with the same indications, precautions and warnings as the approved pioneer product. The route of administration (intravaginal) and the dosage form (intravaginal insert) are the same for the generic and pioneer products. The strength of the active ingredient, progesterone, in the proposed product will be slightly higher than that in the pioneer product due to different active release profile between the proposed and pioneer products. Because the proposed product has a slower release of progesterone from the silicone than the pioneer product, a higher strength of progesterone can be used to allow for similar dose administration per animal between the proposed and pioneer products.

While the proposed generic product differs in strength of the active ingredient as compare to the pioneer product, the dose of progesterone administered per animal will be similar to that of the pioneer product, as demonstrated in a bioequivalence study.

Environmental Impact

In accordance with 21 CFR 25.33(a)(1), Intervet Inc. requests a categorical exclusion from the requirement to file an environmental impact assessment for this action, as the generic drug will be marketed under the same conditions of approval as the previously approved animal drug.

Economic Impact

Information pertaining to the economic impact of this petition will be submitted if requested by the commissioner.

Differences Between Pioneer and Proposed Generic Product Labeling

The changes in the labeling noted below may not be placed in the same areas as they are located on the pioneer product. The changes noted will be reflected in the proposed drug product's labeling in an appropriate manner so that it is clear and readily understood by the end-user.

References to "EAZI-BREED™ CIDR® Cattle Insert" will be changed to "CueMate" as appropriate throughout the labeling.

The EAZI-BREED™ CIDR® Cattle Insert name and logo will be removed and replaced with the new brand name logo throughout the labeling.

The product number will be changed.

The NADA number will be changed.

The sponsor information will be changed.

Under Net Contents and Active Ingredient:

Levels of progesterone per device of "1.38" will be changed to "1.56" grams.

Certification

Bioniche Animal Health USA, Inc. certifies that this suitability petition contains all information know to them that is unfavourable to the petition.

Cindy Hickey

Cindy Hickey
V.P. Corporate Quality & Regulatory Affairs
Bioniche Life Sciences Inc.

August 20, 2004
Date